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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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| UNITED STATES OF AMERICA,<br><br>Plaintiff,<br><br>v.<br><br>ABLE LABORATORIES, INC., a Corporation, and MURTY VEPURI, PAUL MANNING, and MARK FENTON, Individuals,<br><br>Defendants. | ) | Civil Action No. 91-4916 (AJL JW)<br><br>COMPLAINT FOR INJUNCTION |

The United States of America, plaintiff, by Michael Chertoff, United States Attorney for the District of New Jersey, respectfully represents to this Honorable Court as follows:

1. In this action, plaintiff, United States of America, seeks a statutory injunction to restrain defendants, Able Laboratories, Inc. ("Able"), a corporation, and Murty Vepuri, Paul Manning, and Mark Fenton, individuals, from manufacturing and distributing in interstate commerce adulterated drugs, in violation of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 301 et seq. Jurisdiction to restrain such

violations is granted to federal district courts by the Act, 21 U.S.C. § 332(a).

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1391(c).

3. Defendant Able Laboratories, Inc., is incorporated in the State of New Jersey, is licensed to do business by the State of New Jersey, and is doing business at 6 Hollywood Court, South Plainfield, New Jersey, within the jurisdiction of this Court.

4. Defendant Murty Vepuri, an individual, is the Chief Executive Officer of Able Laboratories, Inc. As such, he is responsible for and has authority over the operations of the firm, including the ability to make changes in the quality control and manufacturing procedures utilized by the firm. Mr. Vepuri performs his duties as Chief Executive Officer of Able at 6 Hollywood Court, South Plainfield, New Jersey.

5. Defendant Paul Manning, an individual, is the President of Able Laboratories, Inc. As such, he is responsible for all of the company's activities. Mr. Manning performs his duties as President of Able at 6 Hollywood Court, South Plainfield, New Jersey.

6. Defendant Mark Fenton, an individual, is the Vice President for Quality and Technical Affairs of Able Laboratories, Inc. As such, he is responsible for the daily operations of the

firm. Mr. Fenton performs his duties as Vice President of Able at 6 Hollywood Court, South Plainfield, New Jersey.

7. The defendants have been and are now engaged at their plant at 6 Hollywood Court, South Plainfield, New Jersey, in the manufacture, processing, testing, packing, labeling, storing, and distributing in interstate commerce of articles of drug within the meaning of 21 U.S.C. 321(g)(1), and holding for sale articles of drug after shipment of one or more of their components in interstate commerce.

8. The drugs manufactured by the defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) in that the methods used in, and the facilities or controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with Current Good Manufacturing Practices ("CGMP") to ensure that such drugs meet the requirements of the Act as to safety and have the identity and strength, and meet the quality and purity characteristics, which they purport and are represented to possess. CGMPs for all drugs are set out in U.S. Food and Drug Administration ("FDA") regulations at 21 C.F.R. Parts 210 and 211.

9. The defendants violate 21 U.S.C. § 331(a) by introducing and delivering for introduction into interstate commerce or causing to be introduced and delivered for

introduction into interstate commerce articles of drug, which are adulterated as set forth in Paragraph 7.

10. The defendants violate 21 U.S.C. § 331(k) by their act of manufacturing, processing, packing, and labeling, or causing to be manufactured, processed, packaged, and labeled, articles of drug, in that these acts are done by the defendants while the articles are held for sale after shipment of one or more of their components in interstate commerce, and result in the articles being adulterated as set forth in Paragraph 7.

11. FDA conducted a comprehensive inspection of the defendants' plant from June 11, 1991, to August 6, 1991. That inspection disclosed the following deviations from current good manufacturing practice, among others:

a. Retesting of lots without explanation [21 CFR 211.160];

b. Discarding stability samples that failed to meet potency specifications with no explanation [21 CFR 211.160];

c. Inadequate laboratory equipment used for calibration [21 CFR 211.160(4)];

d. Failure to have, and failure to follow, written procedures for release testing [21 CFR 211.165];

e. Failure to complete scheduled stability tests [21 CFR 211.166];

f. Inadequate review and control over record keeping [21 CFR 211.100];

g. Inadequate review and control over the release of in-process drug products [21 CFR 211.22];

h. Failure by the firm's laboratory unit to keep adequate and complete records [21 CFR 211.194];

i. Inadequate packaging and labeling controls [21 CFR 211.125];

j. Incomplete validation of the firm's manufacturing processes, failure to follow validation protocols, and failure to document the validation of significant changes in manufacturing processes [21 CFR 211.110];

k. Failure to conduct complete annual reviews of all products [21 CFR 211.180(e)].

12. Previous FDA inspections of the defendants' plant in April, 1986, May, 1988, September, 1988, May, 1989, February, 1990, October, 1990, and February, 1991, established CGMP violations in virtually all of the firm's product lines, demonstrating the defendants' inability or unwillingness to make comprehensive changes to their manufacturing processes in order to comply with CGMP regulations and to operate their facility in compliance with the Act. Although defendants have promised to correct specific deficiencies noted by FDA, and have in fact corrected some of these deficiencies, defendants have failed repeatedly to make the corrections for all of their products.

13. Plaintiff is informed and believes that, unless enjoined by this Court, the defendants may well continue to violate 21 U.S.C. §§ 331(a) and 331(k) in the manner herein alleged.

WHEREFORE PLAINTIFF PRAYS:

I. That the defendants, Able Laboratories, Inc., a corporation, and Murty Vepuri, Paul Manning, and Mark Fenton, individuals, and each and all of their officers, agents, servants, employees, and attorneys and those persons in active concern or participation with them or any of them, be perpetually restrained and enjoined from directly or indirectly doing or causing to be done any of the following acts:

A. introducing or delivering for introduction into interstate commerce any articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

B. manufacturing, processing, packing, or holding for sale at defendants' facility any article of drug after shipment of one or more of its components in interstate commerce, which act of manufacturing, processing, packing or holding causes such drug to be adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

II. That the plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

Dated this _____ day of _____, 1991.

Respectfully submitted,

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